



OCT 22 2004

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Bionutritional International Inc.
3064 Michigan Avenue
Kissimmee, FL 34744

To Whom It May Concern:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.bionutritional.com> and has concluded that claims on this web site cause your products CarboGetic™, Metabo Fat Blocker™, and Extreme Carb Blocker to be misbranded under the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: <http://www.fda.gov>.

Under section 403(r)(6) of the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met. [21 U.S.C. § 343(r)(6)(A).] One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading. [21 U.S.C. § 343(r)(6)(B).]

The labeling of CarboGetic™, Metabo Fat Blocker™, and Extreme Carb Blocker bears structure/function claims, including the following:

- CarboGetic™:
 - "[A] product that inhibits the absorption of carbohydrates while increasing your energy levels to burn more fat and carbs."
 - "Blocks carb absorption via alpha-amylase inhibition"
 - "Helps reduce sugar cravings"
 - "Controls carb cravings"
 - "CarboGetic™ [contains] ingredients designed to help reduce cravings, while preventing carbohydrates from being digested and converted into sugar that eventually gets stored in the body as fat."
 - "CarboGetic™ helps you reduce starch calories by blocking alpha-amylase...When CarboGetic™ inhibits this process;[sic] the undigested starch

and its calories simply pass through the body undigested. This blocking of starch calories helps you lose weight, greatly helping you maintain your weight for years to come.”

Under "Ingredients" for CarboGetic™:

- “CarboVal™-Phaseolus Vulgaris (extract): is a starch blocker that has been proven to neutralize the starch (carbs) consumed in a meal.”
- “Korean Ginseng...a good appetite suppressant.”
- “Chromium polynicotinate-Results of a clinical study published show that chromium polynicotinate aids in the loss of body fat. The data clearly confirms that supplementation with chromium picolinate can lead to significant improvements in body composition resulting from fat loss, particularly for individuals who may not be as aggressive in making lifestyle changes....”

Under "FAQs" for CarboGetic™:

- “CarboGetic™... help[s] to reduce cravings, while preventing carbohydrates from being digested and converted into sugar that eventually gets stored in the body as fat.”

• Metabo Fat Blocker™:

- “Metabo Fat Blocker™ ... can bind to dietary fat and provide a feeling of fullness - thus suppressing the appetite.”
- “Binds with the fat you eat - reducing the amount of fat you absorb”
- “[O]n average, most people who weigh 180-260 pounds can lose about 7-10 pounds a week with our Metabo Fat Blocker™.”

• Extreme Carb Blocker:

- “Extreme Carb Blocker helps you reduce starch calories by blocking alpha-amylase.... [T]he undigested starch and its calories simply pass through the body undigested.”
- “[I]nhibits the absorption of carbohydrates and sugar.”
- “Blocks carb absorption...”
- “Helps reduce sugar cravings
- “Controls carb cravings”

Under "Ingredients" for Extreme Carb Blocker:

- “Phaseolus Vulgaris (extract): is a starch blocker that has been clinically shown to neutralize up to 66 percent of the starch consumed in a meal.”

We have reviewed these claims and have concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or

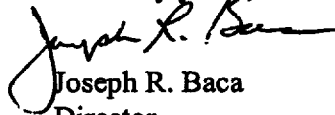
misleading, and cause your product to be misbranded within the meaning of sections 403(a)(1) and 403(r)(6)(B) of the Act. [21 U.S.C. § 343(a)(1), (r)(6)(B).] It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded. [21 U.S.C. § 331(a).] It is a violation of section 301(k) of the Act to commit any act with respect to a food if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. [21 U.S.C. § 331(k).]

This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action, including seizure or injunction, without further notice.

If you have scientific evidence which you believe substantiates that your claims for CarboGetic™, Metabo Fat Blocker™, or Extreme Carb Blocker are truthful and not misleading, please provide it to us within fifteen (15) working days of receipt of this letter. Alternatively, please advise this office, in writing and within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to ensure that similar violations do not occur in the future. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be sent to the attention of Compliance Officer Quyen Tien at the above address.

Sincerely yours,



Joseph R. Baca

Director

Office of Compliance

Center for Food Safety and Applied Nutrition